# **PXWire** A Quarterly Update on HIV Prevention Research

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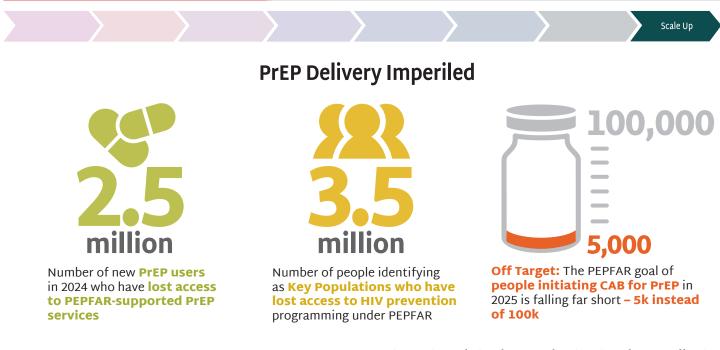
### From Research to Rollout: A global snapshot of HIV prevention



*PxWire is AVAC's quarterly update covering the latest in the field of biomedical HIV prevention research, development, implementation and advocacy. Each publication includes updates, emerging issues and upcoming events.* 

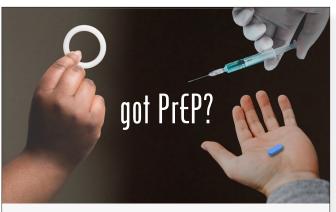
The field of HIV prevention is confronted with two opposing forces; programs for delivering PrEP have been shuttered all over the world by the withdrawal of the US government from global health. At this same moment in history, next-generation long-acting products hold great promise to accelerate HIV prevention and help the world achieve epidemic control. Navigating these seismic developments requires unprecedented coordination, solidarity, and courage. Global health champions can defy the hatred, fear, and greed that are dominating politics in so many places around the world. Together we can innovate, create, and protect the advance of HIV prevention and global health. This issue provides a snapshot on threats to delivering PrEP, the potential of injectable lenacapavir (LEN) for PrEP, and on the implications of upstream research and development of other long-acting PrEP.

# Progress in PrEP Uptake: Threatened



> PEPFAR documented 2.5 million new PrEP users in 2024, who could now lose access to PEPFAR-supported PrEP services. US Department of State issued a limited and inconsistently implemented waiver in February, allowing for continued provision of HIV treatment but restricting PrEP access to pregnant and lactating people only.

- These actions will result in 3.5 million who identify as key populations (KPs) losing access to all HIV prevention programming under PEPFAR, according to 2024 PEPFAR data tracking KP use of PrEP. These groups have higher rates of HIV incidence and face additional barriers to accessing services now that targeted programs are suspended.
- PEPFAR had a goal of 100,000 people initiating cabotegravir (CAB) for PrEP in 2025. But only 5,000 individuals had initiated by October 2024. The suspension of PEPFAR funding imperils scale-up of this long-acting product.
- These figures represent just some of the disruptions that are decimating PrEP delivery. Learn more here: Impact of PEPFAR Stop Work Orders on PrEP
- Overcoming this challenge, restoring, sustaining, and accelerating PrEP access is imperative and possible if the field works together.

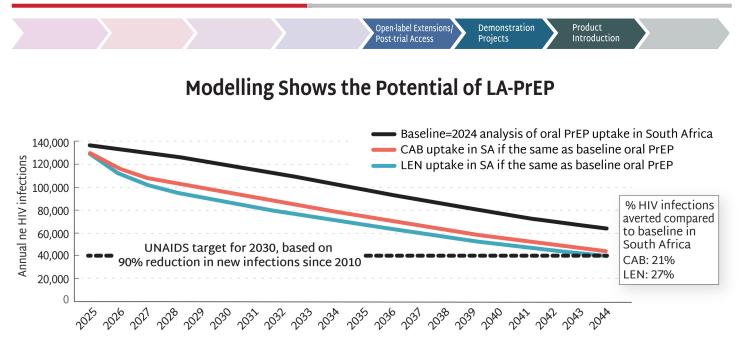


For the last eight years, AVAC has proudly worked with PEPFAR to document PrEP uptake and its impact around the world. That ended in January with a stop work order from the US government. But protecting access to PrEP is vital. Are you leading a PrEP program? Whether supported by PEPFAR or not, we invite you to work with us to ensure global data on PrEP is not lost.

Find us at **PrEPWatch@AVAC.org** 



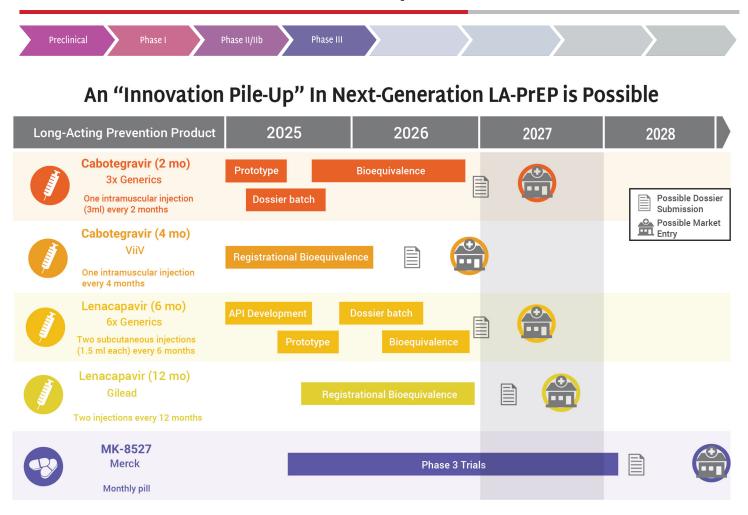
### **PrEParing for New Products**



Adapted from Lenacapavir: Preliminary impact, cost effectiveness and cost threshold for South Africa, presented to the South African PrEP Technical Working Group in 2024 by Lise Jamieson, Gesine Meyer-Rath and Leigh Johnson.

- Approval by the US Food and Drug Administration (FDA) for injectable 6-month LEN for PrEP is expected in June, with WHO guidelines expected in July. See the full timeline.
- Modelling data from South Africa demonstrate the potential of injectable PrEP to dramatically reduce HIV incidence by up to 90% by 2044, and potentially even sooner with more aggressive uptake. This potential goes beyond South Africa, lighting the way toward epidemic control the world over.
- The field must be prepared for swift action once LEN is approved and recommended, to ensure this opportunity is not squandered. As AVAC's interactive timeline, *Tracking LEN Rollout*, outlines, donors, ministries of health, manufacturers, regulators, and civil society all have a role to play to pave the way for swift, equitable and effective introduction of LEN for PrEP.

### The Latest R&D in the Prevention Pipeline



- The HIV prevention market is headed toward a period of significant opportunity—and possible congestion as a slate of new products are on track for continued development and potential introduction to the market in 2027 and 2028.
- Generics for 2-month CAB and 6-month LEN, along with ViiV's 4-month CAB, Gilead's 12-month LEN, and Merck's monthly oral MK-8527 PrEP pill (if further development and approvals are successful) could all enter the market by 2028.
- The possibility of so many products on the market, including four different formulations of injectable PrEP, means that it is imperative the field prepares for this future now.

- Markets and policies must be built to support the products in the market already, so that new options can be rapidly deployed and deliver impact. Otherwise, the field will squander time and money, with epidemic control slipping further out of reach.
- With US funding cuts to both HIV prevention R&D and delivery, communities must be engaged, supported, and informed about all prevention options, and the choices that all stakeholders will need to make. This means gathering and sharing data and information about cost-effectiveness, user acceptability, program feasibility, and impact. Communities empowered with the facts can advocate for the choices they need, and push ministries of health to make strategic investments and procure the prevention method mix that fits their context and delivers impact.

## **Prevention Playlist**

AVAC develops a wide range of resources to inform decision making and action. Check out the latest:

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#### Subscribe to Global Health Watch

AVAC's weekly newsletter dedicated to breaking down critical developments in US policies and their impact on global health, at avac.org/global-health-watch.

#### CHANGE

In response to the unfolding crisis, more than 1,500 people from civil society organizations around the world have launched CHANGE—Community Health & HIV Advocate Navigating Global Emergencies—a coalition formed to support urgent action: contact.change.2025@gmail.com

# ह् USE

- Research Matters Advocacy Toolkit, AVAC
- Tracking the Freeze:Real-Time Impact on Key Populations, GBGMC
- ➡ Impact of the Stop-Work Order on PrEP, AVAC
- 🔿 Tracking Lenacapavir Rollout, AVAC
- PEPFAR Program Impact Tracker, Impact Counter
- Weekly Situation Report, UNAIDS

### **© WATCH/LISTEN**

- Politics and Global Health: The Need for a New, Resilient Architecture, Webinar
- Lawsuit Wins and What's at Stake: AVAC v US Department of State, PxPulse episode
- Global Health in the Lurch: What's happening now and who is pushing back, PxPulse episode
- Advancing Sexual and Reproductive Health and Rights: Moving forward post-the 2024 US Election, Webinar

# 🖧 READ

- Despite USG Global Health Collapse, Here Are Several Data Trackers To Support Your Advocacy, AVAC
- On Going Backwards, Lancet
- The Trump Administration's Foreign Aid Review: Status of PEPFAR, KFF
- The Best Investment You Didn't Know You Made: How NIH Funding Fuels Innovation and Economic Growth, amfAR
- ➔ HIV Market Impact Memo, CHAI
- The USAID List of Terminated Global Health Awards What Does it Tell Us?, KFF
- AVAC Condemns HHS Mass Layoffs
- *PrEP in the Balance: Hopes and fears in 2025*
- Better Engagement, Better Evidence: Working in partnership with patients, the public, and communities in clinical trials with involvement in good participatory practice, Lancet
- PEPFAR: A Strategic Necessity for US Leadership and Global Health, AVAC
- S Rallying for HIV Prevention Amid Policy Attacks, AVAC
- CROI 2025 Shows the Promise of Research at its Best, AVAC

### About AVAC



AVAC is an international non-profit organization that leverages its independent voice and global partnerships to accelerate ethical development and equitable delivery of effective HIV prevention options, as part of a comprehensive and integrated pathway to global health equity. Follow AVAC on Bluesky @HIVpxresearch; find more at www.avac.org, www.prepwatch.org and www.stiwatch.org.